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βeta βlockers

Wireless Blood Pressure Monitor

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Document Revision History

Revision Number	Revision Date	Description	Rationale
0	10/09/2013	First Draft	Compilation of all sections by each team member
1.0	11/01/2013	Gate Review Draft	Revisions based off stake holder and peer review
2.0	11/13/2013	Baseline	Revisions based off gate review presentation

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1. Product Concept

This section describes the general idea for the wireless blood pressure monitoring system. The product will include a home blood pressure monitor, similar to ones that are already in many households, that will have Wi-Fi capabilities and user authentication, and access to a web service, which will record and display data on the condition of the user, primarily regarding his or her blood pressure. This product will allow patients and their doctor to more easily track the patient's blood pressure and coordinate what they may need to do to improve their health.

1.1 Purpose and Use

The purpose of this product is to allow patients to have an easy way to monitor their health, and to see how their blood pressure has changed over time. A patient can also connect to their doctor through the web service, so that the doctor can keep track of the patient and offer advice or suggestions, without having to schedule an appointment. As the system continues to gather data from a patient, it will begin to offer advice of its own if it finds that the patient's current condition fits a certain condition or pattern, and could alert both the doctor and patient if the patient's health is concerning, which could help reduce how often the doctor has to check on the patient.

Clinical studies have shown that for patients who have high blood pressure, keeping in contact with their doctor or caretaker and informing them of their blood pressure results as they continue to take them often allows them to stabilize their blood pressure to healthy levels more quickly and effectively. The goal of this product is to expedite that process, so that patients do not have to write down their results, they do not have to constantly call, email, or visit their doctor, and their doctor does not have to in turn keep all of this information and track the patient themselves. Instead, the patient will authenticate themselves on their monitor, take their blood pressure, and go on with their day. Later, they and their doctor can log into the website and see how the patient's latest result compared with their previous results, and take any appropriate actions.

The entire system should be easy to use, and is comprised of two separate subsystems: the blood pressure monitor system, which will handle authenticating the user and measuring their blood pressure, and the remote web system. Users will need to establish a connection from their monitor to their Wi-Fi service in order for the monitor to begin uploading data, and they will need to create a user account and setup their authentication credentials on the web service in order to authenticate successfully and begin storing their results. After the monitor measures their blood pressure, the users can log into the website and see the results.

1.2 Intended Audience

The target audience is mostly middle-age consumers, 30 to 60 years of age, people that often are at risk for blood pressure issues but are still able to use and understand new technology. Younger people may purchase the product, but considering they are not nearly as at risk for health issues regarding blood pressure, there will be less interest from this demographic. Older audiences may have relatively greater difficulty in understanding and using the system, so the design will not be as oriented to handle their demographic as for the middle-aged audience.

This product is intended to be clean and simple to use, but it may end up being pricey considering the use of newer technology is being incorporated into the monitor. There is an assumption that the majority of the targeted audience will have an accessible Wi-Fi access point to an active internet service. It is also assumed that those using the product will have a doctor willing to participate in the process of the system.

Another way to sell the device would be to supply the monitors to the doctors and caretakers, who could then lend or rent out the device to their patients. In this case, the quantity of the device would be as many as selling to individuals, but perhaps it would be used by more people who only need it for short-term use.

2. Product Description and Functional Overview

This section provides the reader with an overview of the wireless blood pressure monitor. The primary operational aspects of the product, from the perspective of the end users, maintainers and administrators, are defined here. The key features and functions found in the product, as well as critical user interactions and user interfaces are described in detail.

2.1 Features and Functions

The wireless blood pressure monitoring system is made up of two subsystems: the blood pressure monitor and the web service. The blood pressure monitor is an electronic blood pressure reading monitor that allows the user to take non-invasive blood pressure readings periodically to record blood pressure levels over periods of time for evaluation. The monitor will use an oscillometric method to determine the wearer's blood pressure reading from an automatically inflating and deflating cuff worn on the upper or lower arm.

Whenever a user begins a session the monitor initializes and requires authentication to validate the user's identity. The monitor cuff will take one or more blood pressure readings, display the results, and immediately transmit the data to a server via a wireless connection. In the event that a wireless connection cannot be established, the monitor will store the user's blood pressure readings temporarily until a connection is re-established. The user can use the monitor at any point in time to check their blood pressure level by wearing the cuff and powering on the device using the power/start button. In that way, the blood pressure monitor can support multiple users.

After authenticating and taking blood pressure readings, the users data is transmitted to the devices corresponding website where the user has an account created for them by their regular doctor or clinic personal that administer their medical records. The data transmitted to the server will be encrypted for security and will contain a user identifier to associate the user's blood pressure readings with their account.

To create an account, the user's doctor will be required to input information about the user, such as their age, gender, diet, physical activity, medical history, and prescription history. Upon completion the user's profile is ready to use requiring the doctor to send the users temporary login credentials through a secure channel. The user will then have to change their login credentials for their web profile.

The website will have two distinct profile types: one belonging to the user, and one belonging to doctors. From the website, the doctor will be able to create their own account profile.

The users account will have a profile page that graphically displays all the users' results in various tables and graphs, make annotations on any specific blood pressure, create alerts for their doctor, or allow the system to generate alerts if it detects irregularities or generally alarming blood pressure levels.

The second profile belongs to doctors. This profile will allow a user's doctor to keep tabs on the user(s) that they have created by allowing them to see their information and readings, to communicate with the user through a message system, to receive alerts when the user or system thinks something is wrong, and to create a new user web account. Because it was the doctor that created the users account they are automatically tethered to that user and are connected through a patient-doctor relationship.

2.2 External Inputs and Outputs

The system is made up of two distinct subsystems where different user inputs are expected with different resulting outputs. The subsystems are the blood pressure monitor (including the cuff) and the website. The diagram below illustrates user interaction with the different subsystems.

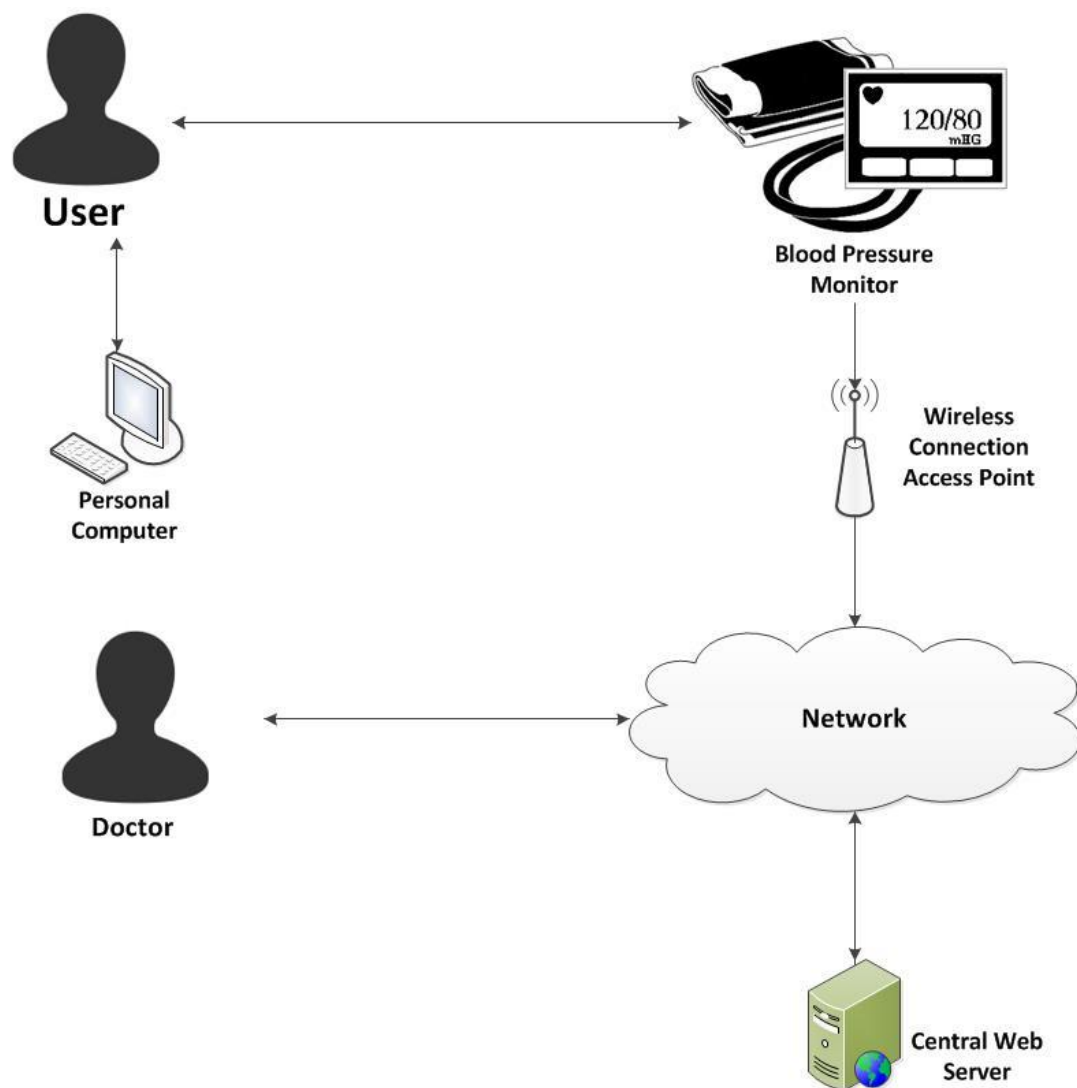


Figure 2- 1

The Blood Pressure Monitor

Input	Output
Device Setting and Configurations	Warnings, Alerts, Messages
Wireless Connection Credentials	Data Transmission
User Authentication	
Start/Stop Commands	Power on/Power off
Blood Pressure	BP Readings

Table 2 - 1

To begin using the blood pressure monitor for the first time, the user will need to have a web account setup for them by their primary doctor. Once the account is set up, the user must enter their web connectivity credentials into the device so that when blood pressure readings are taken they can begin transmitting the data. Then, the user must enter their authentication credentials into the device to complete the setup.

After the initial setup, the user will put the blood pressure cuff around their arm. After telling the device to start by hitting the corresponding buttons, the cuff will automatically inflate and deflate to take the user's blood pressure. Various sensors will activate to take in the input required to determine blood pressure. The monitor will show the user the results, and then transfer them to their web service account to view later.

When using the device, the user should avoid certain factors that could lead to inaccurate readings. Such factors include, but are not limited to, measuring blood pressure after taking any medications, exercising, immediately after awaking, distressing, or consuming alcohol, caffeine, or tobacco. Because the device has no way of determining these factors, the user must ensure that they avoid these situations.

Web Service Account

Input	Output
User Information	Charts and Graphs
Profile Connections	Advice System
Messaging System	System Alerts

Table 2 - 2

To access the website the user will need to have a web service account setup for them. The user account setup will be administered by the user's primary doctor or clinical personal and will require information on the user such as their name, login credentials, gender, age, diet, exercise routines, medical history, and prescription history. After setting up the account, the user will need to input their authentication credentials to be allowed into the site.

Various other forms of input are expected from the different modules of the website. To manage certain aspects of their account, a user has to enter or modify the information that their account privileges allows them to; or when needing to connect to a doctor or family profile, the user has to input the profile for connection and a mutual agreement from both profile holders is required.

In turn the system will allow the user access to their data upon successful authentication. And the system will generate the charts and graphs of the user's data.

2.3 Product Interfaces

The user will interface with the monitor when needing to take blood pressure readings and the website when needing to view records or access the other modules.

Monitor interface

User interfacing with the blood pressure monitor takes place when user needs to check blood pressure levels. Interfacing with the monitor will include entering authorization credentials, sending start/stop commands through GUI screens; and viewing recent blood pressure levels through a display.

Website interface

Create Account

The screenshot shows a web application titled "Patient Setup" for "Medical Group LLC". The page has a navigation bar with "Home" and "Logout" links. On the left, there are four vertical menu items: "Personal Info", "Diet/Exercise", "Medical History", and "Perscriptions". The main content area is titled "Does patient have a history of blood pressure" and includes a "Yes" (checked) / "No" radio button selection. Below this is a "Type" dropdown menu with "Hypertension" and "Hypotension" options. Further down, a section titled "Select all that apply" contains a grid of checkboxes for various medical conditions. The "First Heart Attack" checkbox is checked, while all others are unchecked.

Select all that apply		
☒ First Heart Attack	☐ Obesity	☐ Acute Coronary Syndrome
☐ Second Heart Attack	☐ High Cholesterol	☐ Arrhythmia
☐ Cardiovascular Disease	☐ Depression	☐ Anemia
☐ Diabetes	☐ Anxiety	☐ Blood Clots

Figure 2- 2

This is an example of what the patient account setup page will look like. The user’s doctor will be able to enter information, and will select other information from provided lists and radio buttons to create a full profile for the user.

User Blood Pressure Records

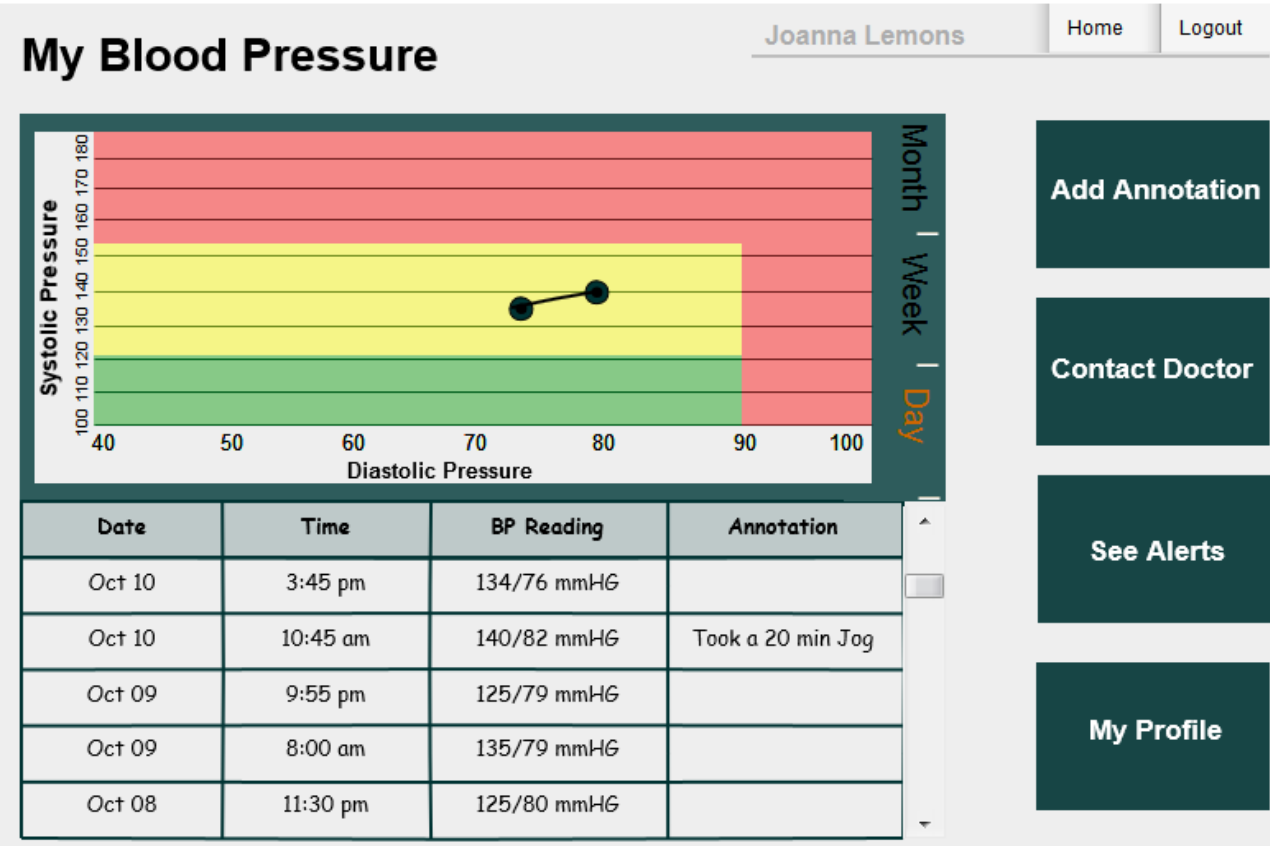


Figure 2- 3

This is an example of a graph that a user would see upon logging into their profile. These graphs will be dynamic and can change to fit what a user would like to see. Note the annotation located at the table of blood pressure readings, to let their doctor and family know that the spike in their blood pressure was in part the result of a 20 minute jog.

Alert System

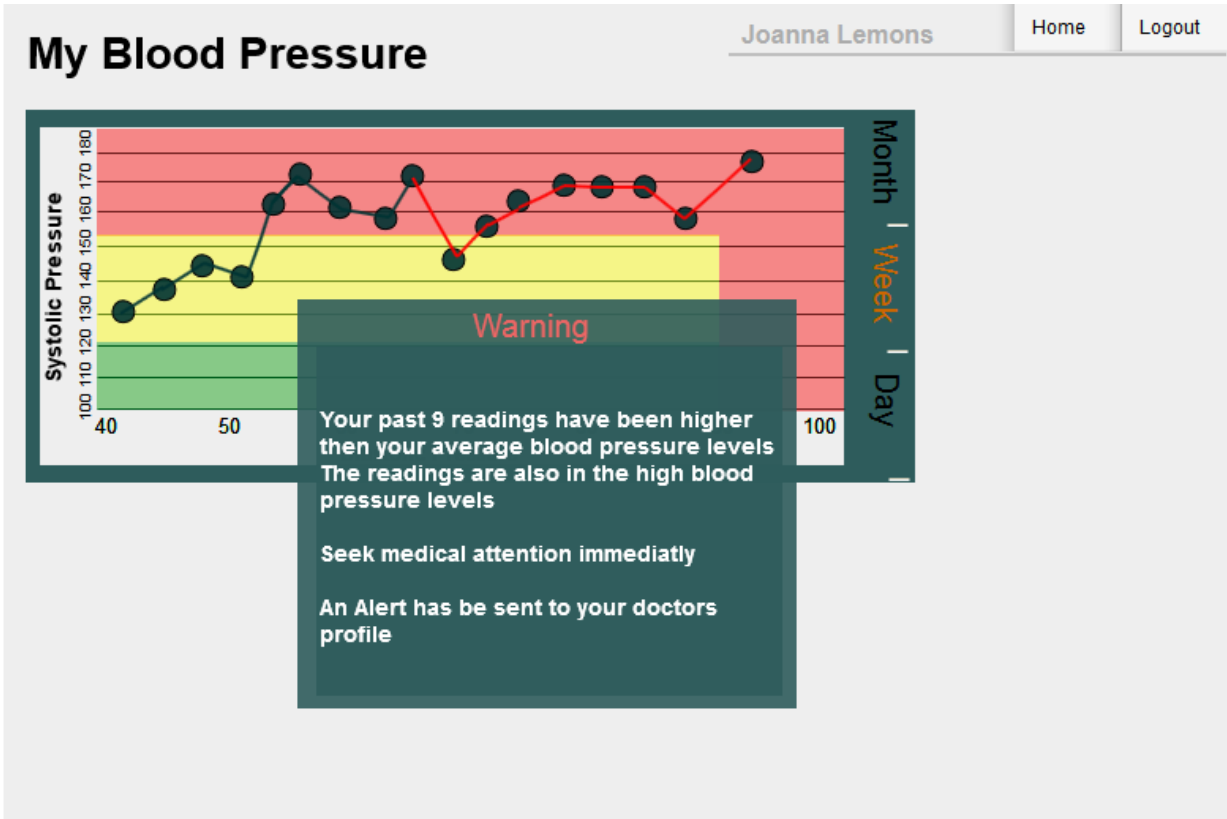


Figure 2- 4

This is an example of an alert to the user of their relatively high blood pressure levels warning them to seek medical attention from their doctor. The user’s irregular high blood pressure levels generated this warning.

3. Customer Requirements

This section will cover the requirements and expectations set by the customer and team Beta Blockers. These requirements will clearly and concisely define what the product will and will not do. The core requirements of the blood pressure monitor will be to read a user's blood pressure and securely transmit it to the product web service, which will process and display the readings to the user.

3.1 Non-invasive Measurements

3.1.1 Description: Blood Pressure Monitor will take readings in a non-invasive manner.

3.1.2 Source: Beta Blockers

3.1.3 Constraints: N/A

3.1.4 Standards: N/A

3.1.5 Priority: 1 – Critical

3.2 Oscillometric Method

3.2.1 Description: Blood Pressure Monitor will use the oscillometric method to evaluate blood pressure.

3.2.2 Source: Beta Blockers

3.2.3 Constraints: N/A

3.2.4 Standards: N/A

3.2.5 Priority: 1 – Critical

3.3 Automatic Inflation/Deflation

3.3.1 Description: Blood Pressure Cuff will automatically inflate and deflate.

3.3.2 Source: Beta Blockers

3.3.3 Constraints: N/A

3.3.4 Standards: N/A

3.3.5 Priority: 1 – Critical

3.4 Cuff Location

3.4.1 Description: The Blood Pressure Cuff will be worn on the upper or lower arm.

3.4.2 Source: Beta Blockers

3.4.3 Constraints: N/A

3.4.4 Standards: N/A

3.4.5 Priority: 1 – Critical

3.5 User Authentication

3.5.1 Description: An authentication system will be used before all sessions to ensure user security.

3.5.2 Source: Beta Blockers

3.5.3 Constraints: Monitor/phone implementation

3.5.4 Standards: N/A

3.5.5 Priority: 1 – Critical

3.6 Blood Pressure Reading

3.6.1 Description: The device will measure the blood pressure of the user it is attached to.

3.6.2 Source: Beta Blockers

3.6.3 Constraints: N/A

3.6.4 Standards: Medical Standards

3.6.5 Priority: 1 – Critical

3.7 View Results

3.7.1 Description: Users will be able to view their results on the monitor.

3.7.2 Source: Beta Blockers

3.7.3 Constraints: N/A

3.7.4 Standards: N/A

3.7.5 Priority: 1 – Critical

3.8 Multiple Readings

3.8.1 Description: Users will be able to record and submit multiple readings in a session.

3.8.2 Source: Beta Blockers

3.8.3 Constraints: N/A

3.8.4 Standards: N/A

3.8.5 Priority: 2 – High

3.9 Result Transmission and Storing

3.9.1 Description: The monitor will transmit the blood pressure results to the website's database for storage.

3.9.2 Source: Beta Blockers and sponsor

3.9.3 Constraints: Database size.

3.9.4 Standards: Secure, store up to five years' worth of readings

3.9.5 Priority: 1 – Critical

3.10 Web Service

3.10.1 Description: A web service will be created to display results, handle users, and house other features.

3.10.2 Source: Beta Blockers

3.10.3 Constraints: N/A

3.10.4 Standards: N/A

3.10.5 Priority: 1 – Critical

3.11 Account Types

3.11.1 Description: The web service will support two types of accounts: patients and doctors.

3.11.2 Source: Beta Blockers

3.11.3 Constraints: N/A

3.11.4 Standards: N/A

3.11.5 Priority: 1 – Critical

3.12 Doctor Account Creation

3.12.1 Description: Doctors will be able to create their own account on the web service.

3.12.2 Source: Beta Blockers

3.12.3 Constraints: N/A

3.12.4 Standards: N/A

3.12.5 Priority: 1 – Critical

3.13 Patient Account Creation

3.13.1 Description: Doctors will create patient profiles and have them connected to their own. The doctor will enter medical information and other key information about the patient's health. The system, with the doctor's permission, will then send an email to the patient's email address with temporary login information. The patient will then change their login credentials, add their personal information (if they wish), and confirm the changes.

3.13.2 Source: Sponsor

3.13.3 Constraints: N/A

3.13.4 Standards: N/A

3.13.5 Priority: 1 – Critical

3.14 Patient's Doctor

3.14.1 Description: A person who wishes to use this system as a patient must be affiliated with a doctor or caretaker who has an account on the web service.

3.14.2 Source: Sponsor

3.14.3 Constraints: N/A

3.14.4 Standards: N/A

3.14.5 Priority: 1 – Critical

3.15 Doctor Limit

3.15.1 Description: A patient may only have one doctor account tied to their account on the web service. If the patient wishes to have more doctors view their data, those doctors will have to use the patient's viewing account to see the information.

3.15.2 Source: Sponsor

3.15.3 Constraints: N/A

3.15.4 Standards: N/A

3.15.5 Priority: 1 – Critical

3.16 Doctor Editing

3.16.1 Description: Doctor accounts can have their information edited by the account holder.

3.16.2 Source: Beta Blockers

3.16.3 Constraints: N/A

3.16.4 Standards: N/A

3.16.5 Priority: 3 - Moderate

3.17 Patient Editing

3.17.1 Description: Profile information (email, password, full name) can be edited by the given patient. Medical information will be edited by the patient's doctor

3.17.2 Source: Sponsor

3.17.3 Constraints: N/A

3.17.4 Standards: N/A

3.17.5 Priority: 1 – Critical

3.18 View Charts and Graphs

3.18.1 Description: All registered users on the site will be able to view various charts and graphs on the website that describe the patient's blood pressure conditions, overall health, and other factors, assuming that they have access to said patients information.

3.18.2 Source: Beta Blockers

3.18.3 Constraints: N/A

3.18.4 Standards: N/A

3.18.5 Priority: 1 – Critical

3.19 Annotations

3.19.1 Description: Patients registered on the site will be able to make notes about particular readings of theirs on the website, to relay information such as changes in their health or lifestyle.

3.19.2 Source: Sponsor

3.19.3 Constraints: Web language used

3.19.4 Standards: N/A

3.19.5 Priority: 2 – High

3.20 Patient Viewing Profile

3.20.1 Description: All patients will have a viewing profile, a way in which friends, family members, other doctors, or anyone else the patient wishes to give access to can view how the patient is doing and other information. This profile is separate from the standard Patient profile, it will be tied to the account with a separate set of login credentials, and it is extremely limited in functionality. The patient will be able to change the login credentials for this at any time to restrict access.

3.20.2 Source: Beta Blockers

3.20.3 Constraints: N/A

3.20.4 Standards: N/A

3.20.5 Priority: 3 – Moderate

3.21 Create Alerts

3.21.1 Description: Alerts can be created, either automatically by the system if it detects a problem or a concerning trend, or by a patient if they want to alert their doctor about something, which will be sent to the doctor for later viewing.

3.21.2 Source: Beta Blockers

3.21.3 Constraints: N/A

3.21.4 Standards: N/A

3.21.5 Priority: 2 – High

3.22 View Alerts

3.22.1 Description: Doctors will be able to view alerts and the issue they pertain to.

3.22.2 Source: Beta Blockers

3.22.3 Constraints: N/A

3.22.4 Standards: N/A

3.22.5 Priority: 2 – High

3.23 Messaging System

3.23.1 Description: Doctors and patients can send messages to one another to be read later (like an email system), as a way of addressing things not covered by the alert system and the annotation system.

3.23.2 Source: Beta Blockers

3.23.3 Constraints: The two parties attempting to message each other must be connected (the doctor created the patient account, or the patient added the family member to their account)

3.23.4 Standards: N/A

3.23.5 Priority: 4 - Low

3.24 Multiple Users

3.24.1 Description: The blood pressure monitor will be able to support multiple users on the same device.

3.24.2 Source: Beta Blockers

3.24.3 Constraints: N/A

3.24.4 Standards: N/A

3.24.5 Priority: 4 – Low

3.25 Login to Access Data

3.25.1 Description: Users will have to log into the website in order to view any data.

3.25.2 Source: Beta Blockers

3.25.3 Constraints: N/A

3.25.4 Standards: N/A

3.25.5 Priority: 1 – Critical

3.26 HIPAA

3.26.1 Description: Product will comply with all HIPAA standards (as well as other standards that apply to medical data) to ensure customer privacy. This will be covered in detail in the Security Requirements section.

3.26.2 Source: Beta Blockers

3.26.3 Constraints: N/A

3.26.4 Standards: N/A

3.26.5 Priority: 1 – Critical

3.27 Advice System

3.27.1 Description: The website will be able to give patients health information, advice, and general suggestions to keep their blood pressure in check by looking at general patterns and user information

3.27.2 Source: Sponsor

3.27.3 Constraints: N/A

3.27.4 Standards: N/A

3.27.5 Priority: 1 – Critical

3.28 Manual Upload of Information

3.28.1 Description: In the case where a patient's wireless connection goes down or begins to suffer problems, the device will store the patient's readings for a set amount of time. The patient will then be able to manually upload the readings using a computer, if they feel that the wireless connection will not resume working in the near future.

3.28.2 Source: Sponsor

3.28.3 Constraints: N/A

3.28.4 Standards: N/A

3.28.5 Priority: 5 – Future

4. Packaging Requirements

The blood pressure monitoring system will come with pre-assembled parts and will be ready to use. User will be able to easily configure the device and start taking readings. All readings will be automatically sent to the website when wifi is enabled or available. Users will have an account created for them by their primary doctor to view and log past readings. The blood pressure monitoring system will be packaged according to these requirements.

4.1 Blood Pressure Cuff

4.1.1 Description: The product will be packaged with a standard blood pressure cuff. The cuff will weigh between ½ -1 pound, and will be fitted for arm circumference of 9-14 inches

4.1.2 Source: Beta Blockers

4.1.3 Constraints: None

4.1.4 Standards: AAMI

4.1.5 Priority: 1 – Critical

4.2 Blood Pressure Monitor

4.2.1 Description: The product will come packaged with a monitor which is attached to the cuff. It will be the interaction point between the patient and the system. The patient can authenticate, take blood pressure reading, view current readings in the session, and send blood pressure readings to the website. The Monitor will be a 3 x 4 inch display and will weigh no more than 6 ounces.

4.2.2 Source: Beta Blockers

4.2.3 Constraints: None

4.2.4 Standards: None

4.2.5 Priority: 1 – Critical

4.3 Android Phone

4.3.1 Description: The product will require an Android phone, which will not be packaged with the product. The phone will use the Android application to interact with the blood pressure monitor device.

4.3.2 Source: Beta Blockers

4.3.3 Constraints: None

4.3.4 Standards: None

4.3.5 Priority: 2 – High

4.4 Android Application

4.4.1 Description: An android application will be provided via Google play store. The application will allow the user to interact with the blood pressure cuff to authenticate, take blood pressure reading, and send the readings to the website.

4.4.2 Source: Beta Blockers

4.4.3 Constraints: Android 3.0+, UNIX

4.4.4 Standards: None

4.4.5 Priority: 2 – High

4.5 Software Packaging

4.5.1 Description: All software will be installed prior to packaging. No set up will be required by the Patient.

4.5.2 Source: Beta Blockers

4.5.3 Constraints: N/A

4.5.4 Standards: N/A

4.5.5 Priority: 1 – Critical

4.6 Website

4.6.1 Description: The team will create a website that will receive blood pressure readings from the device. These readings will be displayed on the website in chart and graph format. The patient will be able to annotate, view advice regarding the readings, send and receive alert messages as well as contact their doctor through the website.

4.6.2 Source: Beta Blockers

4.6.3 Constraints: HIPAA Business Associate Agreement

4.6.4 Standards: N/A

4.6.5 Priority: 1 – Critical

4.7 Battery

4.7.1 Description: The device will be operated via battery power. Batteries will not be packaged with the device.

4.7.2 Source: Beta Blockers

4.7.3 Constraints: N/A

4.7.4 Standards: N/A

4.7.5 Priority: 3 - Moderate

4.8 Connection Cable

4.8.1 Description: Connection cable will be provided to manually upload the data on to a computer and uploaded to the website if wifi is not available.

4.8.2 Source: Beta Blockers

4.8.3 Constraints: None

4.8.4 Standards: None

4.8.5 Priority: 5 – Future

4.9 User Manual

4.9.1 Description: A user manual will be provided with the product. The Manual will contain detailed information regarding the product, website, and how to operate the device.

4.9.2 Source: Beta Blockers

4.9.3 Constraints: None

4.9.4 Standards: None

4.9.5 Priority: 2 – High

5. Performance Requirements

This section covers the operational aspects of the entire system, including the physical device on hand and the web service implemented. Some of the performance requirements included in this section are derived from the ANSI/AAMI SP10.2002 standard for automated blood pressure monitors.

5.1 Storage conditions

5.1.1 Description: The blood pressure monitor shall maintain the performance requirements specified in this document after being stored for 24 hours at 21°C (70°F), give or take 10°C variance, and at a relative humidity lower than 90% (noncondensing).

5.1.2 Source: Beta Blockers

5.1.3 Constraints: None

5.1.4 Standards: N/A

5.1.5 Priority: 2 – High

5.2 Operating conditions

5.2.1 Description: The blood pressure monitor shall maintain the safety and performance characteristics specified in this document during operation over the following ranges of environmental conditions:

- a) Temperatures between 11°C and 31°C;
- b) Relative humidity under 90% (noncondensing)

5.2.2 Source: Beta Blockers

5.2.3 Constraints: The blood pressure monitor is set up in its normal operating configuration;

5.2.4 Standards: N/A

5.2.5 Priority: 2 – High

5.3 Operational Battery Life

5.3.1 Description: The blood pressure monitor shall maintain the performance characteristics specified in this document for at least 30 minutes while running the measurement acquisition process continuously.

5.3.2 Source: Beta Blockers

5.3.3 Constraints: The blood pressure monitor is set up in its normal operating configuration; the battery has been fully charged no longer than 1 hour prior to use and fully inspected to be free of defects or malfunction.

5.3.4 Standards: N/A

5.3.5 Priority: 2 – High

5.4 WLAN Authentication Latency

5.4.1 Description: The blood pressure monitor interface to the end-user's wireless local area network (WLAN) will take no longer than 10 seconds to attempt a successful connection. After 10 seconds, the blood pressure monitor will cease the connection activity.

5.4.2 Source: Beta Blockers

5.4.3 Constraints: None

5.4.4 Standards: N/A

5.4.5 Priority: 2 – High

5.5 WLAN Connection Failure Response Time

5.5.1 Description: The blood pressure monitor interface to the end-user's wireless local area network (WLAN) will take no longer than 10 seconds, intervene appropriately, and notify the end-user of the current status of the WLAN connection.

5.5.2 Source: Beta Blockers

5.5.3 Constraints: None

5.5.4 Standards: N/A

5.5.5 Priority: 2 – High

5.6 Web Authentication Latency

5.6.1 Description: The blood pressure monitor interface to the internet and to the web service will take no longer than 30 seconds to attempt a login. After 30 seconds, the system will cease the login activity.

5.6.2 Source: Beta Blockers

5.6.3 Constraints: The web server provides a decent amount of computing performance.

5.6.4 Standards: N/A

5.6.5 Priority: 2 – High

5.7 Blood Pressure Monitor Consistency Regarding Battery Life

5.7.1 Description: The blood pressure monitor will still be able to take consistent readings until the device detects that the battery's voltage is too low to continue normal operation. The variation in blood pressure readings shall be confined to within 15% accuracy.

5.7.2 Source: Beta Blockers

5.7.3 Constraints: The blood pressure monitor is set up in its normal operating configuration; the user should keep his or her physical condition relatively the same when performing the compared readings.

5.7.4 Standards: N/A

5.7.5 Priority: 2 – High

5.8 Blood Pressure Monitor Accuracy

5.8.1 Description: The blood pressure measurements obtained using the monitor shall not deviate more than 10% at any measurement range from an existing commercial blood pressure monitor.

5.8.2 Source: Beta Blockers

5.8.3 Constraints: The blood pressure monitor is set up in its normal operating configuration; the user should keep his or her physical condition relatively the same when performing the compared readings.

5.8.4 Standards: N/A

5.8.5 Priority: 2 – High

5.9 Blood Pressure Monitor Mechanical Robustness

5.9.1 Description: The blood pressure monitor shall be able to maintain its performance and safety requirements when being physically handled during normal use.

5.9.2 Source: Beta Blockers

5.9.3 Constraints: The blood pressure monitor is set up in its normal operating configuration and in good condition from previous uses, if any.

5.9.4 Standards: N/A

5.7.5 Priority: 2 – High

5.10 Blood Pressure Monitor Startup Delay

5.10.1 Description: The blood pressure monitor shall be able to boot up from a cold start to a ready state for the user within 30 seconds.

5.10.2 Source: Beta Blockers

5.10.3 Constraints: The blood pressure monitor is set up in its normal operating configuration.

5.10.4 Standards: N/A

5.10.5 Priority: 3 – Moderate

6. Safety Requirements

This section defines the safety requirements which specify the operational characteristics of the system to ensure the safety of the system's users. The product will be developed as a working prototype for in-house demonstration and testing, the blood pressure monitor development will not follow all of the ANSI/AAMI SP10.2002 standards, and if any of the said requirements are derived from the standard, it is explicitly noted.

6.1 Maximum Cuff Pressure

6.1.1 Description: For devices intended for public, home, or other unsupervised use, a means of limiting cuff pressure shall be provided so that the maximum cuff pressure will never exceed 300 mmHg. For devices intended for use under professional supervision, a means of limiting cuff pressure shall be provided so that the maximum cuff pressure will never exceed 300 mmHg or 30 mmHg above the upper limit of the instrument's manufacturer-specified operating range, whichever is lower. In addition, the device shall incorporate means to ensure that cuff pressure will not be maintained above 15 mmHg for longer than 3 minutes (min).

6.1.2 Source: ANSI/AAMI SP10.2002

6.1.3 Constraints: None

6.1.4 Standards: ANSI/AAMI SP10.2002 "4.3.1 Devices incorporating automatic inflation systems"

6.1.5 Priority: 1 – Critical

6.2 Cuff Pressure Release

6.2.1 Description: An easily accessible and clearly labeled means of allowing the user to deflate the cuff shall be provided. During the rapid exhaust of the pneumatic system with fully-opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg shall not exceed 10 s.

6.2.2 Source: ANSI/AAMI SP10.2002

6.2.3 Constraints: None

6.2.4 Standards: ANSI/AAMI SP10.2002 "4.3.1 Devices incorporating automatic inflation systems"

6.2.5 Priority: 1 – Critical

6.3 Electrical Safety

6.3.1 Description: The blood pressure monitor shall not be able to deliver a harmful shock to its user. The voltage range throughout the device will be limited to 12 volts. The device will also only use DC type power as its primary source of electrical power.

6.3.2 Source: Beta Blockers

6.3.3 Constraints: None

6.3.4 Standards: N/A

6.3.5 Priority: 2 – High

6.4 Eligible Users

6.4.1 Description: The blood pressure monitor shall not be intended for neonatal users. It will be only intended for those who understand how to operate the device safely.

6.4.2 Source: Beta Blockers

6.4.3 Constraints: None

6.4.4 Standards: N/A

6.4.5 Priority: 2 – High

6.5 Blood Pressure Monitor Mechanical Safety

6.5.1 Description: The blood pressure monitor, primarily the wearable components, shall not be able to easily induce physical injury to the user through its physical form.

6.5.2 Source: Beta Blockers

6.5.3 Constraints: None

6.5.4 Standards: N/A

6.5.5 Priority: 2 – High

7. Maintenance and Support Requirements

This section details how the team will ensure that the project is easy to understand, maintain, and improve. It also discusses how the team plans to provide a means with which to support the product from a maintenance perspective should it be released into the market, including how the web service would be maintained and controlled, and how the blood pressure monitor would be handled.

7.1 User Manual

7.1.1 Description: A general user manual will be created that will instruct the end-user on how to safely operate the blood pressure monitor and access his or her information on the website.

7.1.2 Source: Beta Blockers

7.1.3 Constraints: None

7.1.4 Standards: N/A

7.1.5 Priority: 2 – High

7.2 Blood Pressure Monitor Battery Replacement

7.2.1 Description: The battery on the blood pressure monitor shall be replaceable, as it will be found on the consumer marketplace. The battery shall also be able to be removed easily from the device by the targeted audience without compromising the safety and performance requirements.

7.2.2 Source: Beta Blockers

7.2.3 Constraints: None

7.2.4 Standards: N/A

7.2.5 Priority: 2 – High

7.3 Web Service Software Portability

7.3.1 Description: The web service software shall be able to be deployed via an automated script that sets up the server software (e.g. Apache, MySQL, etc.) and preloads system templates such as database schemas and defaults. This is intended to ease deployment onto the client's intended web servers.

7.3.2 Source: Beta Blockers

7.3.3 Constraints: None

7.3.4 Standards: N/A

7.3.5 Priority: 2 – High

7.4 Web Service Software Update Effects

7.4.1 Description: The web service will be able to be modified without having to reboot the operating system or web server (e.g. Apache). There is no guarantee that the web application itself will not restart.

7.4.2 Source: Beta Blockers

7.4.3 Constraints: None

7.4.4 Standards: N/A

7.4.5 Priority: 3 – Moderate

7.5 Web Service Administration Layer

7.5.1 Description: The web service shall have a portal for the system administrators to manage the basics of the web portal so that the source of the web application does not need to be modified and redeployed. This includes website-wide notifications/alerts, the ability to enable/disable certain services, and enabling/disabling the entire web application.

7.5.2 Source: Beta Blockers

7.5.3 Constraints: Does not compromise the security requirements.

7.5.4 Standards: N/A

7.5.5 Priority: 3 – Moderate

8. Security Requirements

This section defines the security requirements of the system. The security requirements are derived from the Health Insurance Portability and Accountability Act (HIPAA) and apply to all protected health information (PHI) that will be collected and stored under the scope of this project. PHI is information that can be used to tie any health-related information to a unique individual. The security of PHI is critical to protect the privacy of all users of the system.

8.1 Data Transport Encryption

8.1.1 Description: The web service shall encrypt all data, particularly PHI, that is transmitted between the blood pressure monitor and the data collecting web server. This requirement is primarily focused on the level of the communication between monitor-client and the web server and not the WLAN connection (see section 8.5).

8.1.2 Source: Beta Blockers

8.1.3 Constraints: None

8.1.4 Standards: HIPAA

8.1.5 Priority: 1 – Critical

8.2 Authorization

8.2.1 Description: The collected PHI data will only be accessible to authorized personnel using audited access controls. Mechanisms will be designed and implemented to ensure that data can be accessed only by appropriate users. This requirement may rely on storage encryption (section 8.4) to prevent unauthorized access, as well as on the web hosting vendor to comply with the HIPAA Business Associate (section 8.7) to maintain control over low-level access to the web server's functionality.

8.2.2 Source: Beta Blockers

8.2.3 Constraints: None

8.2.4 Standards: HIPAA

8.2.5 Priority: 1 – Critical

8.3 Integrity

8.3.1 Description: The system will attempt to prevent any PHI that will be collected and stored from the user from unauthorized modification or corruption and ensure its validity. This requirement may rely on storage encryption (section 8.4) and authorization protocols (section 8.2) to deter unauthorized modification.

8.3.2 Source: Beta Blockers

8.3.3 Constraints: None

8.3.4 Standards: HIPAA

8.3.5 Priority: 2 – High

8.4 Storage Encryption

8.4.1 Description: All PHI data that is being stored or archived will be encrypted and intended for storage of a minimum of five years. In general, the data will be encrypted using symmetric encryption of at least AES-128 strength. The encrypted data can only be decrypted and accessible by users with the appropriate keys. The keys will further be protected using a form of public key encryption. This requirement would also further enforce the protocols of authorization (section 8.2) on PHI data.

8.4.2 Source: Sponsor

8.4.3 Constraints: None

8.4.4 Standards: HIPAA

8.4.5 Priority: 2 – High

8.5 Disposal Guarantee

8.5.1 Description: PHI data, when found necessary to remove from the system, will be effectively purged. This guarantees that when the system removes the data from its oversight, it would be thoroughly deleted from itself and all of the system's underlying dependencies. If a data backup system is implemented (section 8.7), then this requirement will be implemented completely on this system as well. This means that the backups must be thoroughly cleansed of or recompiled without the appropriate data.

8.5.2 Source: Sponsor

8.5.3 Constraints: None

8.5.4 Standards: HIPAA

8.5.5 Priority: 4 – Low

8.6 WLAN Connection Security

8.6.1 Description: The wireless network connection between blood pressure monitor and the WLAN router shall communicated through an encryption of at least a symmetric encryption of AES-128 strength.

8.6.2 Source: Beta Blockers

8.6.3 Constraints: None

8.6.4 Standards: N/A

8.6.5 Priority: 4 – Low

8.7 Data Backup

8.7.1 Description: The data collected by the web portion of the system will be backed up in case of an emergency or accidental deletion situation. The backup must be securely handled (i.e. encrypted and placed under an access control paradigm).

8.7.2 Source: Beta Blockers

8.7.3 Constraints: None

8.7.4 Standards: HIPAA

8.7.5 Priority: 5 – Future

8.8 Business Associate

8.8.1 Description: The system will have a HIPAA Business Associate Agreement with every vendor that has access to the data. The vendor, in the scope of the project, is the company that will host the system's web application. The web hosting company will have all the data that is being transferred and stored, so putting an agreement in place will ensure that the company will follow the HIPAA requirements for the data and the servers. This guarantees that the web hosting company will provide an infrastructure that meets HIPAA compliance requirements. The development team will then be responsible for applying secure programming methodologies to design and manage the website so that its functionality is HIPAA compliant.

8.8.2 Source: Beta Blockers

8.8.3 Constraints: None

8.8.4 Standards: HIPAA

8.8.5 Priority: 5 – Future

9. Other Requirements

This section discusses miscellaneous requirements that did not fit under any of the other given requirements sections. These requirements, while still important to the project, cover things that are highly specific, and generally do not fit under any given label, but they are too sparse to be grouped under a new section of requirements.

9.1 Web Browser Compatibility

9.1.1 Description: The web interface shall be accessible and usable through popular web browsers for the user, caretaker/physician, and administrators. Such web browsers would include Internet Explorer, Mozilla Firefox, Google Chrome, and Safari.

9.1.2 Source: Beta Blockers

9.1.3 Constraints: None

9.1.4 Standards: N/A

9.1.5 Priority: 1 – Critical

9.2 Blood Pressure Monitor Source Compatibility

9.2.1 Description: The blood pressure monitor device's source code shall be compatible with Windows 7 development environments for implementation, deployment, and maintenance.

9.2.2 Source: Beta Blockers

9.2.3 Constraints: None

9.2.4 Standards: N/A

9.2.5 Priority: 1 – Critical

9.3 Web Service Source Compatibility

9.3.1 Description: The source code of the web service functionality shall be compatible with Windows 7 and popular Linux development environments for implementation, deployment, and maintenance.

9.3.2 Source: Beta Blockers

9.3.3 Constraints: None

9.3.4 Standards: N/A

9.3.5 Priority: 1 – Critical

9.4 Smartphone Device Constraint

9.4.1 Description: Any implementation of functionality for mobile devices, mainly smartphones, will be constrained to Android 3.0+ and Unix-type operation systems. This is due to their accessibility and availability of their tools. The choice of Android 3.0 and up is due to their available and compatible feature set for this project.

9.4.2 Source: Beta Blockers

9.4.3 Constraints: The approach of using the smartphone as the primary user interface for the blood pressure monitor to connect to the WLAN, and communicate and process data with the web server over the internet is taken.

9.4.4 Standards: N/A

9.4.5 Priority: 4 – Low

9.5 Multiple Health Modules for Website

9.5.1 Description: The website will be able to support many different sets of data from many different pieces of hardware, such as blood sugar readings or weight measurements, to allow for a robust web service that will allow doctors to easily track patients with a wide variety of conditions or concerns.

9.5.2 Source: Beta Blockers

9.5.3 Constraints: None

9.5.4 Standards: N/A

9.5.5 Priority: 5 – Future

9.6 Advanced Authentication Capabilities

9.6.1 Description: The monitor will have advanced authentication capabilities, to better ensure that the correct person is wearing the device at all times.

9.6.2 Source: Beta Blockers

9.6.3 Constraints: None

9.6.4 Standards: N/A

9.6.5 Priority: 5 – Future

9.7 Remote Control for Blood Pressure Monitor

9.7.1 Description: The blood pressure monitor will come with a control that will be used to control the system, allowing for more portability and removing the need for a phone or a large box to support the system.

9.7.2 Source: Beta Blockers

9.7.3 Constraints: None

9.7.4 Standards: N/A

9.7.5 Priority: 5 – Future

10. Acceptance Criteria

The following criteria must be met for the wireless blood pressure monitor to be a complete product. Due to the sensitivity of the data involved these guidelines must conform to HIPAA standards.

10.1 Verify that the data is secured.

10.1.1 Requirement(s) addressed:

Requirements Number	Name
3.25	Login to Access Data
3.26	HIPPA
8.1	Data Transport Encryption
8.2	Authorization
8.3	Integrity
8.4	Storage Encryption
8.5	Disposal Guarantee
8.6	WLAN Connection Security
8.8	Business Associate
8.9	Device Reading Storage Time Limit

Table 10 - 1

10.1.2 Verification Procedure:

Data will be encrypted using HIPPA standards and verified with the sponsor of the project. The data encryption will be tested using various data penetration tools to ensure a reasonable level of encryption is used. And the data transfer and online database are secure.

10.2 Verify that the blood pressure reading is accurate.

10.2.1 Requirement(s) addressed:

Requirements Number	Name
3.6	Blood Pressure Reading
3.7	View Results
3.8	Multiple Reading
5.8	Blood Pressure Monitor Accuracy

Table 10 - 2

10.2.2 Verification Procedure:

The wireless blood pressure monitor will be tested against other devices to ensure accuracy. Multiple readings and test conditions will be implemented to make sure readings are consistent.

10.3 Verify that the system is user friendly.

10.3.1 Requirement(s) addressed:

Requirements Number	Name
3.10	Web Service
3.18	Charts and Graphs
3.19	Annotations
3.20	Patient Viewing Profile
3.27	Advice System
4.9	Manual

Table 10 - 3

10.3.2 Verification Procedure:

The website and device will be thoroughly tested by the sponsor/customer to ensure user friendliness. The displays and interfaces will be shown to various members of the target demographic to guarantee that they are able to understand how to interact with them.

10.4 Verify the system shall authenticate user login.

10.4.1 Requirement(s) addressed:

Requirements Number	Name
3.5	User Authentication
5.4	Web Authentication Latency
8.1	Data Transport Encryption
8.2	Authorization
8.3	Integrity
8.6	WLAN Connection Security
8.8	Business Associate

Table 10 - 4

10.4.2 Verification Procedure:

The wireless blood pressure monitor will be tested to make sure user authentication is implemented correct. Multiple test cases will be implemented to ensure the system correctly verifies valid credentials as well as invalid credentials.

10.5 Verify the system is safe and noninvasive for the user.

10.5.1 Requirement(s) addressed:

Requirements Number	Name
6.1	Maximum Cuff Pressure
6.2	Cuff Pressure Release
6.3	Electrical Safety
6.5	Blood Pressure Monitor Mechanical Safety

Table 10 - 5

10.5.2 Verification Procedure:

The blood pressure cuff will be tested to make sure it conforms to AAMI standards and is safe for the user.

10.6 Verify the system is giving proper “advice” to the user.

10.6.1 Requirement(s) addressed:

Requirement Number	Name
3.27	Advice System

Table 10 - 6

10.6.2 Verification Procedure:

The team and sponsor will test to see if the system is sending correct messages to the user base on their medical status and blood pressure reading. Data taken from test subjects and hardcoded data will be uploaded to the system to test what advice it administers under different conditions.

10.7 Verify that account creation works and can handle errors

10.7.1 Requirement(s) addressed:

Requirement Number	Name
3.11	Account Types
3.12	Doctor Account Creation
3.13	Patient Account Creation
3.14	Family Account Creation

Table 10 - 7

10.7.2 Verification Procedure:

Multiple accounts will be created for all types of accounts. Different information will be entered for each user, to test what data will be accepted and what will be rejected.

10.8 Verify that charts and graphs are generating and personalized

10.8.1 Requirement(s) addressed:

Requirement Number	Name
3.17	Charts and Graphs

Table 10 - 8

10.8.2 Verification Procedure:

Data (some real, some hardcoded) will be loaded into the database that represents different patients with different conditions and health statuses. The team will log in as these users and view different graphs for each of them, to confirm that they are generating, that they are accurate, and that they adjust dynamically to respond to patterns and the general health of the given patient

10.9 Verify that the alert system works

10.9.1 Requirement(s) addressed:

Requirement Number	Name
3.20	Create Alerts
3.21	Read Alerts

Table 10 - 9

10.9.2 Verification Procedure:

The team will log into different patient accounts and request an alert be sent. Data will also be fed into the system that should trigger the web service's automatic alert system. The team will then log into the different patients' doctors' accounts to see if the alerts went through properly, and are being displayed for the doctor.

10.10 Verify Data Transfer

10.10.1 Requirement(s) addressed:

Requirement Number	Name
3.9	Result Transmission
3.26	HIPPA
8.1	Data Transport Encryption
8.3	Integrity
8.4	Storage Encryption
8.6	WLAN Connection Security
8.8	Business Associate

Table 10 - 10

10.10.2 Verification Procedure:

The team will ensure that the data is encrypted in a way that satisfies HIPAA and other standards needed to be a secure and approved system. The blood pressure monitor will be tested for accuracy and other metrics, during which the data transfer protocol can also be tested by ensuring that the requested data to be transferred gets to the database.

11. Use Cases

The use case section describes how the intended user interacts with the system. There are two main sections of use cases for the blood pressure monitor: the monitor device and the web service. The device section describes how the user interacts with the physical device. The web service section describes how a user interfaces with the website.

11.1 Doctor Account Creation

11.1.1 Scenario: A doctor goes to the website and clicks the doctor Sign Up button. The website displays a form where they enter their profile information. The user then clicks the Create Profile button.

11.1.2 Actor(s): Doctor

11.1.3 TUCBW: The user clicks on the Sign Up button.

11.1.4 TUCEW: The user sees their home screen.

11.2 Patient Account Creation

11.2.1 Scenario: Doctor clicks on the Register Patient button. The website displays a form for the doctor to fill out with the patient personal information. The doctor will specify the patient's name and a temporary password will be generated for that user. After the form is completed the doctor clicks submit, and the patient will be added to the system and to the doctor's patient list.

11.2.2 Actor(s): Doctor

11.2.3 TUCBW: Doctor clicks the Register Patient button.

11.2.4 TUCEW: Doctor sees the patient in his/her list.

11.3 Authenticate User

11.3.1 Scenario: The user will turn on the device or go to the website, and the system shall prompt for a user name and password. The user will enter his/her credential and submit; the system shall verify the credential and redirect the user to the home screen if verification was successful.

11.3.2 Actor(s): Doctor, Patient

11.3.3 TUCBW: The user presses the Log In button/goes to the website.

11.3.4 TUCEW: The patient sees the home screen.

11.4 Take Blood Pressure

11.4.1 Scenario: The patient is logged into the device and the home screen is displayed. The patient then places his/her arm in the device's cuff and presses the start button. The device automatically inflates the cuff and the sensors take a reading. The patient then sees the results displayed on the device screen.

11.4.2 Actor(s): Patient

11.4.3 TUCBW: The patient presses the Start button on the device.

11.4.4 TUCEW: The patient sees the blood pressure results on the device display.

11.5 Edit Profile Information

11.5.1 Scenario: The user clicks the edit profile button. The website displays all the current profile information for the user to edit. The user makes changes to the profile and clicks the save button. The user will be redirected to his/her profile and the newly added changes will be displayed.

11.5.2 Actor(s): Patient, Doctor

11.5.3 TUCBW: The user clicks on edit profile button.

11.5.4 TUCEW: The user sees the updated information on his/her profile.

11.6 Edit Patient Medical Information

11.6.1 Scenario: A doctor, who is logged into the website, selects a patient from their list and clicks the Edit button. The website displays a form with the patient's current medical information. The doctor makes the necessary edits and clicks the Save button.

11.6.2 Actor(s): Doctor

11.6.3 TUCBW: The doctor clicks on the Edit button.

11.6.4 TUCEW: The doctor sees the updated changes on the patient's profile.

11.7 View Charts and Graphs

11.7.1 Scenario: The user clicks on the View Charts button. The website displays charts and graphs based on the selected patient's most recent blood pressure readings.

11.7.2 Actor(s): Doctor, Patient

11.7.3 TUCBW: The user clicks on the View Chart button.

11.7.4 TUCEW: The user sees the charts and graphs of the patient's blood pressure levels.

11.8 Create Annotations

11.8.1 Scenario: The patient clicks on the Blood Pressure Chart button and select a blood pressure reading to annotate. The patient will click the Annotation button and be prompted to enter information and clicks submit. The patient will see the new annotation on the chart next to the reading.

11.8.2 Actor(s): Patient

11.8.3 TUCBW: The patient clicks the Blood Pressure Chart button.

11.8.4 TUCEW: The patient sees the annotation on the reading.

11.9 View Advice

11.9.1 Scenario: The patient logs into the website and clicks the Advice button. The website then generates an advice message based on the patient's most recent blood pressure readings.

11.9.2 Actor(s): Patient

11.9.3 TUCBW: The patient clicks the Advice button.

11.9.4 TUCEW: The patient sees the advice on the website.

11.10 Create Alert

11.10.1 Scenario: A patient is logged into the website. They click on the Set Alert button. The website shows a form with some alert choices. The patient selects an alert option and clicks set alert.

11.10.2 Actor(s): Patient

11.10.3 TUCBW: The patient clicks the Set Alert button.

11.10.4 TUCEW: The patient sees a confirmation message that an alert was sent.

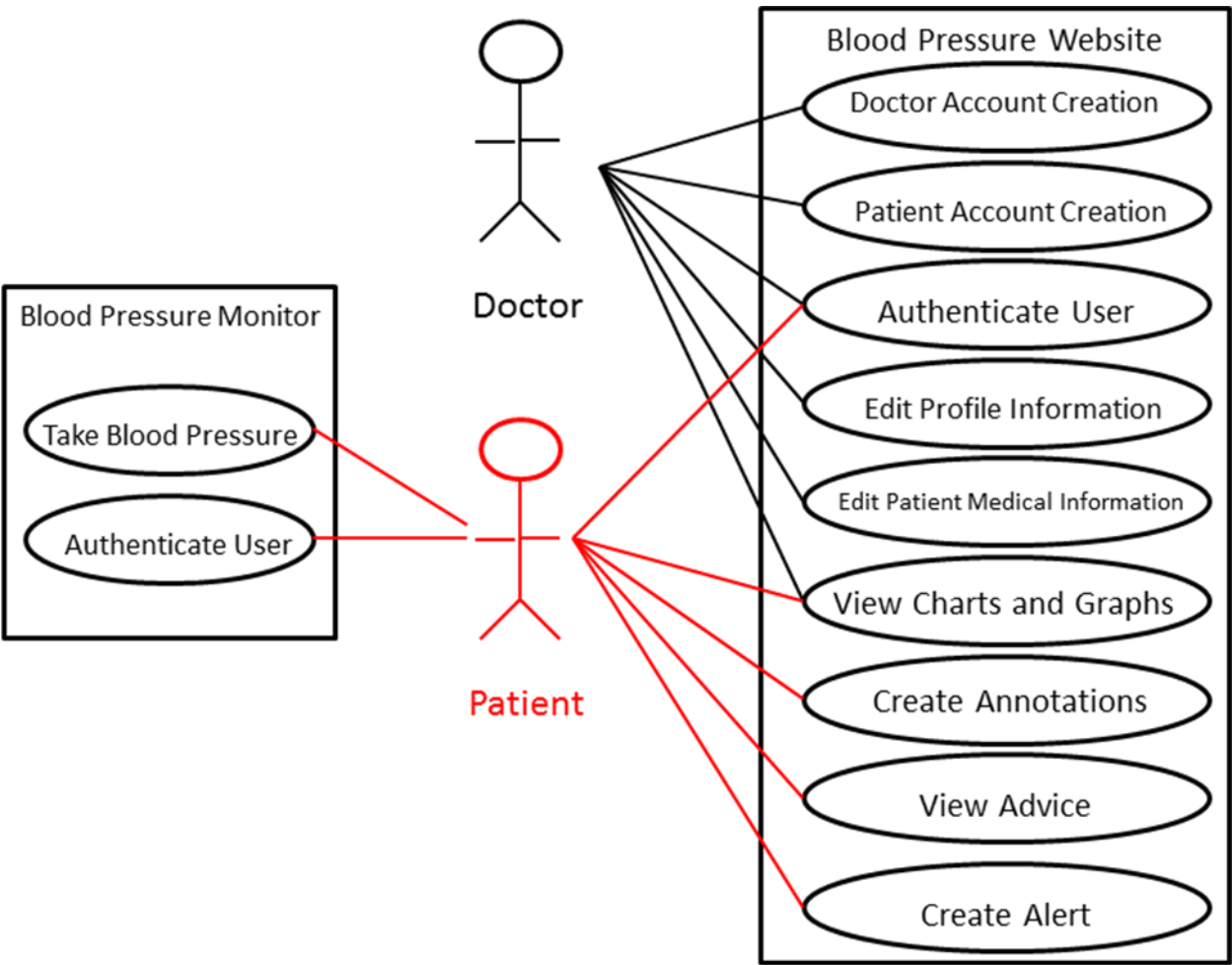


Figure 11- 1

12. Feasibility Assessment

This section provides the reader with a feasibility analysis of the wireless blood pressure monitoring system consisting of the following six components: scope analysis, research, technical analysis, cost analysis, resource analysis, and schedule analysis. Because the system's detailed design specification has not begun, this assessment is based entirely on the team's judgment, knowledge, prior experience, and critical analysis.

12.1 Scope Analysis

The scope of work required for the critical requirements outlined in this document is practical for the given time frame of the project, and prototyping of these requirements by the deadline date appears feasible. This assessment is based on the team's extensive research on the various implementations of blood pressure monitors currently in the market, as well as the team's abilities and skills. The critical requirements include reading human blood pressure levels, storing data regarding the results, transmitting data securely over a wireless connection, and displaying the various tables, graphs, and other modules associated with the website. These critical requirements will be addressed first, and from there the remaining requirements will be addressed gradually based on their priority.

Another aspect that will be addressed as a priority parallel to the mentioned critical requirements is the user friendliness of the system. The device's targeted audience is comprised of middle aged individuals who may or may not be very familiar with technological devices and would not want to be hindered by the device. Therefore, throughout the development of the project, it must be ensured that the device, the website, and the interfaces that the user will interact with are easy to use and understand, and that they would be appealing to users in the targeted age range.

12.2 Research

The development team has placed a considerable emphasis on researching the two largest aspects of the project: the hardware design of the blood pressure monitor, and the software design of the website.

The largest component is the hardware design of the blood pressure monitor and cuff, responsible for controlling motor and valve drivers, pressure sensor readings, signal filtering, display, and transport of data. Based on the research completed, there appears to be a substantial amount of resources for the design and implementation of a standard blood pressure monitor. There also appears to be a standardization of the development of home blood pressure monitoring devices administrated by the AAMI Sphygmomanometer Committee. The standardized requirements clearly identify what aspects of

the system are critical and what are not, giving the development team an idea of what requirements should be made a priority and what should not.

The research done on the hardware design reveals that the development team has three major options in implementing a blood pressure monitoring device – reverse engineering an existing monitor and integrating the necessary components, acquiring a Bluetooth smart ready blood pressure reading device and integrating a remote control or mobile device for user interface, or fabricating a circuit design that will implement the monitor device from analog components. Each implementation has its pros and cons that will have to be considered thoroughly by the development team.

The second largest component of the system is the web service responsible for retrieving, storing, and analyzing the data, messaging and alerting user, and connecting the doctor to the user. The research done on this aspect of the project includes researching hypertension, its causes, contributing factors, and the meaning of a blood pressure reading. This gives the team an understanding of the medical aspect of blood pressure to ensure the system is giving accurate diagnostic. More research will be done in the future as more components of the system come together.

12.3 Technical Analysis

The project's hardware system will be determined by the implementation that the team chooses to design from the three designs researched. Whether reversed engineered, Bluetooth enabled, or fabricated by the development team, the hardware consists of three major parts: the air chamber motor control, the pressure sensor driver, and the wireless connectivity.

The air chamber motor control and pressure sensor will implement an oscillometric method for measuring blood pressure using pneumatic control. The oscillometric method requires that the air chamber motor, made up of a relay valve and a pump, induce the intra-arterial pulsation while the systolic and diastolic pressure (the two pressures read in order to get a blood pressure level) are estimated from the amplitudes of the oscillation using the pressure sensor. The signal being transmitted from the pressure sensor will be filtered and converted into digital signal by an ADC.

The wireless connectivity component will then take care of transmitting that data from the microcontroller unit to the server for handling. This will be implemented using either Bluetooth or Wi-Fi technology. The user interface will be taken care of by an LCD display to present blood pressure readings and mechanical or touch sensing for button/keyboard implementation.

Other technical components of the blood pressure monitor include the power control, and the USB driver control. The block diagram below displays the hardware components contained by the blood pressure monitor device.

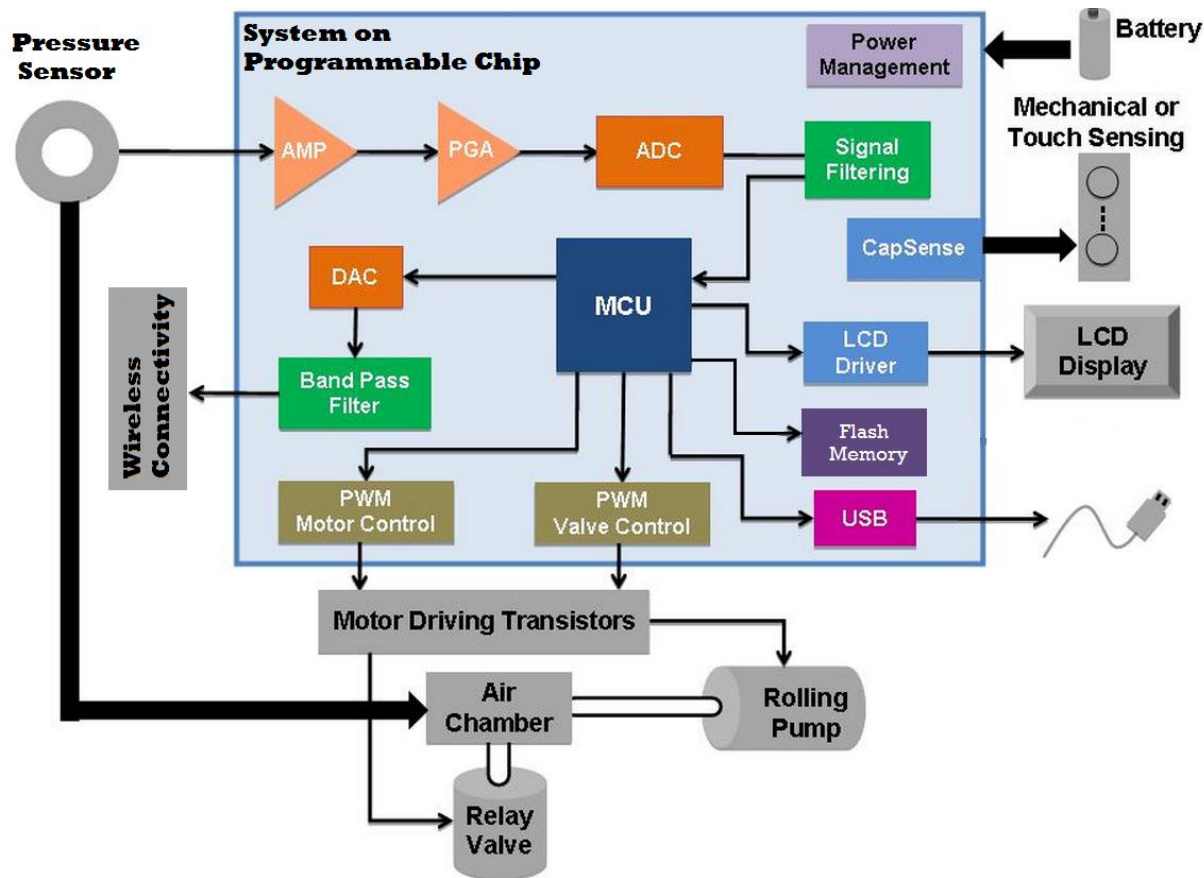


Figure 12- 1

From a software perspective, the web service is composed of the graph and table system, the messaging and alert system, and the advice system, which are all tethered together by the user's profile and information. The graph and table system will take patient's blood pressure results and generate various graphs and charts to give a visual representation of the patient's health. The graphs will adjust their high and low ranges and alerts based on factors such as their general blood pressure (figured over time), medical conditions that could affect blood pressure, and medication and diet. Patients will be able to select certain readings from the graph or chart to mark them and make notes on them, in case they want to say something about that result. There are open source tools to help make the chart generation easier, mostly the team will be dealing with the annotations and the way data will be loaded onto the system.

The messaging and alert system is a way for patients and doctors to interact, so that they can keep in touch and inform each other of things that the service cannot. The alert system will allow the web service to analyze a user's results and send an alert message to the patient's doctor if it detects that the patient's health is outside normal conditions. Again, there may be tools to help facilitate the actual communication, so the team's technical skills will be mostly applied to the algorithm to look for alarming health patterns. The advice module will allow the system to further analyze a person's blood pressure results and other information to dispense recommendations over time, to help take some of the

pressure off of the doctor, although the advice given will have its limits. This will involve a lot of data processing and pattern recognition to find what sort of advice needs to be given. The complexity of this algorithm will depend on how extensive the team wishes to make this feature.

With all of the technical aspects of these features considered, the team believes that they will be able to successfully implement all of these different systems, though backup plans have been prepared in case things don't go as scheduled.

12.4 Cost Analysis

Based on research of the market, the development team predicts that the blood pressure monitor will be completed within the budget requirement. Most of the hardware is available to buy in several specifications and cost variations, giving the team a financial flexibility.

If the team chooses to reverse engineer an existing product then the cost would include the price of the consumer blood pressure monitor plus the price of the components that will be integrated like the wireless connectivity and the USB connectivity. The price of the unit and the components would depend on how much of the planned system is already implemented in the unit. If the team chooses to fabricate the blood pressure monitor, the cost would include the price of each individual piece of hardware as well as the price of printing and surface mounting the circuit board. Regardless, this is where the bulk of the budget will be spent. The only situation where the team could go over the budget would be if the hardware components would get damaged, break, or in the case of fabrication not work on the first setup and replacement parts are needed. If this happened multiple times, the project will quickly become costly.

No cost for the software side is anticipated. The website will not require any specialized software to be purchased, as far as the team is currently aware of. The only possible costs that may be required are the cost of using a web hosting service (if the web service will be deployed through this method), or any costs associated with setting up a web server to house the web service, if any.

Below is a breakdown of the predicted cost of the wireless blood pressure system if the system were reversed engineered and components were integrated:

Item	Cost
Consumer Blood Pressure Monitor	\$80.00
Wireless LAN Module	\$50.00
Single USB Connection Module	\$20.00
Arduino Development Board with WI-FI Capabilities	\$90.00
Web Hosting Service	\$100
Total	\$340

Table 12- 1

Below is a breakdown of the predicted cost of the wireless blood pressure system if the system uses a Bluetooth smart enabled blood pressure monitor with an Android device:

Item	Cost
Bluetooth smart enabled Blood Pressure Monitor	\$120.00
Web Hosting Service	\$100
Google Play Account	\$25
Total	\$245

Table 12- 2

Below is a breakdown of the predicted cost of the wireless blood pressure system if the system were fabricated:

Item	Cost
Analog Components	\$140
Circuit Fabrication and Mounting	\$100
Wireless LAN Module	\$50.00
Single USB Connection Module	\$20.00
Arduino Development Board	\$90.00
Web Hosting Service	\$100
Total	\$500

Table 12- 3

12.5 Resource Analysis

The development team consists of two computer scientist, two software engineers, and one computer engineer. As a team the collective skills and knowledge of each member complements each other, giving a dynamic work structure. When evaluated individually, each member has a unique skill or ability that contributes distinctively to the whole project.

The team's strengths come in the form of programming in Java, C, and multiple web languages, coding to meet specifications, and reverse engineering. Two members of the team have a considerable amount of hardware experience – the first has taken multiple classes in hardware implementation, and the other has had ample experience with robotic design. The other three members have a strong background in programming with multiple languages and platforms.

An area of concern is the team's weaknesses, which include three notable skills essential to the success of the project, test design, product packaging, and secure programming. These skills are important

because of the nature of a medical device needing to be testable for accuracy, and meeting user guidelines and HIPAA regulations.

As the project progresses, more skills will be required that may not have been foreseen. The development team knows from prior experience that they are competent enough to learn new skills and concepts fairly quickly to adapt to the project.

12.6 Schedule Analysis

The development team used two methods to estimate approximately how long the project will take, given certain factors and constraints. The first method the team used was Jones's First Order Estimation. To begin, the projects function points had to be listed, which gave a basic overview of how many components are involved in the system and how complicated they are.

Function Point Analysis				
Program Characteristics	Low Complexity	Medium Complexity	High Complexity	
Number of inputs	4 x 3	2 x 4	0 x 6	20
Number of outputs	4 x 4	2 x 5	0 x 7	26
Inquiries	5 x 3	1 x 4	1 x 6	25
Logical internal files	8 x 7	2 x 10	1 x 15	91
External interface files	2 x 5	0 x 7	0 x 10	10
Unadjusted function-point total				172

Table 12- 4

Table 12-4 shows the results of the analysis of the function points from the system. The team found that a large number of logical internal files will be used by the system, which severely raised the total. The number of outputs, including a couple of relatively complex outputs, also helped to bump the sum up. Ultimately, the team wound up with 172 function points.

Adjustment Factor	Effort Value
	0-5
Data Communication	4
Distributed Data Processing	2
Performance	2
Heavily Used Configuration	2
Transaction Rate	4
On-line Data Entry	4
End-User Efficiency	1
On-line Update	3
Complex Processing	3
Reusability	2
Installation Ease	0
Operational Ease	1
Multiple Sites	0
Facilitate Change	1
Total	29
Adjustment Factor	0.94

Table 12- 5**Formula 1:**

$$\text{Adjustment Factor} = (\text{Total} * 1\%) + .65$$

Table 12-5 shows how the team calculated the influence multiplier (or adjustment factor) needed to calculate Jones' First Order Approximation. The team listed the 14 adjustment factors, and estimated how much effort would be required from various members to complete these factors for the project. Most of the factors ended up in the lower range, with a few of them (mostly ones involving data transmission or web handling) reaching up to a level 4, but never to level 5. After totaling these numbers, Formula 1 was applied to get the adjustment factor.

Unadjusted function-point total	172
Influence multiplier	0.94
Adjusted function-point total	161.68

Table 12- 6

In Table 12-6, the team took the function-point total and multiplied by the influence multiplier to give the adjusted function-point total. The multiplier did little to the total in this case, as it was close to one.

Jones' First Order Estimation			
	Best in Class	Average	Worst in Class
Unadjusted Function Point	8.3	9.1	10.7
Adjusted Function Point	8	8.9	10.4

Table 12- 7

As shown in Table 12-7, from these numbers, the estimated man-months were calculated by multiplying the function points by Jones's First Order Estimation Number. The team found that the project is a business project, so the three numbers were .41, .43, and .46. From these results, it can be seen that in a worst-case scenario, the project will take a little over 10 months to complete. Considering that there are 5 team members, and considering that each team member has other classes and projects, and thus cannot commit a full 40 hours a week, this seems like a relatively reasonable amount of time. This time will allow the team to finish the project, but may prove troublesome if the team falls behind. However, the team found that they have overestimated some of the factors in the project, so a reevaluation of the numbers may bring this number down as the project becomes clearer and certain aspects become more understood.

The second method that was used was the Basic COCOMO method, which takes into account the number of lines of code and the effort expected to be put forth by the team. This is an extremely simple way to calculate the needed time, which can result in a wide range or an overly optimistic or pessimistic number.

Software project	a_b	b_b	c_b	d_b
Organic	2.4	1.05	2.5	0.38
Semi-detached	3	1.12	2.5	0.35
Embedded	3.6	1.2	2.5	0.32

Table 12- 8

Table 12-8 shows the coefficients needed to compute the COCOMO approximation. The team found that the project fit the semi-detached project format, so these coefficients were used in the approximation.

Basic COCOMO Estimation	Low	High	
Effort	14.2	30.8	Person months
Development Time	6.3	8.2	Months
People Required	2.3	3.7	

Table 12- 9

Formula 2:

$$\text{Effort Applied (E)} = a_b (KLOC)^{b_b}$$

Formula 3:

$$\text{Development Time (D)} = c_b (\text{Effort Applied})^{d_b}$$

Formula 4:

$$\text{People required (P)} = \text{Effort Applied} / \text{Development Time}$$

Table 12-9 shows the final estimate of the various results given by the basic COCOMO formula. The Effort is the amount of person months it will require to complete the project, and is given by Formula 2. KLOC is the total lines of code the team expects to write for the project, measured in thousands of lines. For this project, after some assessment, the team agreed that they would likely end up writing between 4 and 8 thousand lines of code. Thus, they will need between 14 and 30 person months to complete the project.

The development time is the time the project is expected to take before it has been fully completed, and is given by Formula 3. The equation gave an estimated development time of about 7 months. Therefore, the project will run considerably longer than the schedule that was allotted. The People Required, given by Formula 4, states that about 3 people are needed to complete the project. Thus, some of this time will hopefully be cut by adding two people. Reevaluation of the projects requirements and scope may need to be done in order to trim time off, but the team feels as though these numbers may be abnormally high due to lack of clarity in some areas of the project, as well as the simplicity of the methods used to do these evaluations, which leads to wide variances in the scale.

13. Future Items

This section describes requirements and features that have been discussed implementing, but due to various constraints or concerns feel that the team will not be able to complete during the duration of this project. These features may be added to a later version of the project, should one be developed, or may end up being dropped for lack of support or need.

13.1 Requirement 3.28: Manual Upload of Information

13.1.1 Description: In the case where a patient's wireless connection goes down or begins to suffer problems, the device will store the patient's readings for a set amount of time. The patient will then be able to manually upload the readings using a computer, if they feel that the wireless connection will not resume working in the near future.

13.1.2 Constraint: Schedule: Due to the teams limited schedule, we do not feel that we will have enough time to deal with the situation of a user doing manual uploads. While it seems like a simple feature, it is of low priority, and the team expects hidden problems to occur when trying to implement it.

13.2 Requirement 4.8: Connection Cable

13.2.1 Description: A connection cable will be provided to manually upload the data onto a computer and uploaded to the website if Wi-Fi is not available.

13.2.2 Constraint: Schedule: See requirement 13.1

13.3 Requirement 8.7: Data Backup

13.3.1 Description: The data collected by the web portion of the system will be backed up in case of an emergency or accidental deletion situation. The backup must be securely handled (i.e. encrypted and placed under an access control paradigm).

13.3.2 Constraint: Schedule: Due to the teams schedule, we do not feel it is in the team's best interest to deal with minute maintenance features while there are still major functional features to create.

13.4 Requirement 8.8: Business Associate

13.4.1 Description: The system will have a HIPAA Business Associate Agreement with every vendor that has access to the data. The vendor, in the scope of the project, is the company that will host the system's web application. The web hosting company will have all the data that is being transferred and stored, so putting an agreement in place will ensure that the company will follow the HIPAA requirements for the data and the servers. This guarantees that the web hosting company will provide an infrastructure that meets HIPAA compliance requirements. The development team will then be responsible for applying secure programming methodologies to design and manage the website so that its functionality is HIPAA compliant.

13.4.2 Constraint: Business practices, and necessity: This is under the assumption that we even end up using a web hosting service or other type of service, and also relies on there being a web hosting service willing to agree to this. Due to the teams schedule and budget, we do not want to focus too much attention on this at this point.

13.5 Requirement 9.5: Multiple Health Modules for Website

13.5.1. Description: The website will be able to support many different sets of data from many different pieces of hardware, such as blood sugar readings or weight measurements, to allow for a robust web service that will allow doctors to easily track patients with a wide variety of conditions or concerns.

13.5.2. Constraint: Schedule/Budget: Due to time constraints, the web service will only be able to support blood pressure readings by the end of this project. Also, the budget does not allow us to purchase and test the various pieces of hardware we would need to create a system for more than one module. Once we establish this as a viable product, however, each additional module would become easier to add from a web perspective.

13.6. Requirement 9.6: Advanced Authentication Capabilities

13.6.1. Description: The monitor will have advanced authentication capabilities, to better ensure that the correct person is wearing the device at all times.

13.6.2. Constraint: Knowledge/Technology: Blood vein analysis and other techniques are being developed to provide a better system for person verification, but these techniques are still very young and not ready to be used extensively, and we lack the time required to fully understand them in their current form.

13.7. Requirement 9.7: Remote Control for Monitor

13.7.1. Description: The blood pressure monitor will come with a control that will be used to control the system, allowing for more portability and removing the need for a phone or a large box to support the system.

13.7.2. Constraint: Schedule: Scheduling issues cause us to have to forgo this option in favor of using a phone for the project. The remote would function similarly to the way the phone application will end up working, but we would have to handle the fabrication of the entire remote, the system to allow the Wi-Fi chip to connect, and the interaction between it and the monitor. Using a phone will allow us to bypass some of these concerns, giving us more time to focus on the website and the monitor.

14. Glossary

wifi – also spelled Wi-Fi, is the name of a wireless networking technology that uses radio waves to provide high-speed network and Internet connections. It is generally used as a synonym for WLAN.

WLAN – wireless local area network.

sphygmomanometer – a synonym for blood pressure monitor.

BPM – acronym for blood pressure monitor.

BP – acronym for blood pressure.

ANSI/AAMI SP10.2002 – an international standard used for blood pressure monitors. It's assumed that all viable BPM's follow this standard.

Bluetooth – a wireless standard for exchanging data over short distances using short wavelength radio transmissions.